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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,504	02/12/2004	Ralph M. Ellison	077319-0399	3667

7590 02/13/2006

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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,504	ELLISON ET AL.	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-24 are pending in this application.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 14-16, drawn to method of treating cancer in a human, wherein the cancer is leukemia, classified in class 424, subclasses 620-629, class 514, subclasses 504, 908.

II. Claim 17, drawn to method of treating cancer in a human, wherein the cancer is a lymphoma, classified in class 424, subclasses 620-629, class 514, subclasses 504.

III. Claim 18, drawn to method of treating cancer in a human, wherein the cancer is a solid tumor not in the central nervous system, classified in class 424, subclasses 620-629, class 514, subclasses 504.

IV. Claim 23, drawn to method of treating cancer in a human, wherein the cancer is a tumor of the central nervous system selected from the group consisting of neuroblastoma, retinoblastoma, glioblastoma or oligodendroglioma, classified in class 424, subclasses 620-629, class 514, subclasses 504.

Claims 1-12, 19-22 and 24 link inventions I to IV. Claim 13 further links inventions I and II. The restriction requirement between the linked inventions is subject to the nonallowance of such linking claims. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any

claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The four different inventions are distinct from each other because of the different cancers that are being treated. In the absence of a nexus type teaching, one having ordinary skill in the art would typically not expect efficacy for one type of cancer to be indicative of efficacy for a different type of cancer.

The search for each of the four different and distinct inventions would be of serious burden. Even though the classification of the inventions are similar due to the fact that U.S. Patent Classification uses the placement rule of active agent as the controlling classification criteria, the state of the art in cancer treatment clearly recognizes the separate status of different cancers as separate subjects for inventive effort. For example, cancer drugs are commonly effective for one type of cancer but not others. Additionally, applicant's separate filings of applications such as 10/649,944

(lymphoma treatment), 10/640,399 (multiple myeloma treatment), 10/649,776 (melanoma treatment) is further evidence of separate recognition in the art of the divergence of the inventive subject matter. Therefore, given the nature of the invention, a significant percentage of relevant prior art would likely not be found in the patent literature. Rather, it is expected that the non-patent literature collection would contain a substantial percentage of the prior art related to the various anti-cancer uses of arsenic. As a result, the four different and distinct inventions, even though they are classified similarly due to the placement methodology of the U.S. classification system, would actually require searching in places (e.g. commercial databases) where no pertinent art to the other inventions may be found. Further, the four different and distinct inventions would have to be evaluated vis-a-vis the prior art four different ways to separately arrive at four different patentability determinations. Given the extensive breadth of prior art related to therapeutic uses of arsenic in humans, the burden posed by such one of the invention groups already amounts to serious burden and any additional burden by having to search and examine more than one invention would place an undue burden on the Examiner.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN PAK
PRIMARY EXAMINER
GROUP 1600